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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,839

Applicant(s)

KREEK ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 84-141 is/are pending in the application.
- 4a) Of the above claim(s) 91-93, 105-108, 113-125 and 127-141 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84-90, 94-104, 109-112 and 126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/5/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of group I in the reply filed on 4/15/05 is acknowledged. The traversal is on the ground(s) that the polypeptide variants of group II are not distinct from the DNA sequences of group I, and further that there would not be serious burden to examine at least those claims of groups I and II together. This is not found persuasive because although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein as evidenced by many of the method claims of the instant invention. Furthermore, the search and examination of the polypeptides and polynucleotides are not coextensive. The inventions have a separate status in the art as shown by their different classifications. The search of the polypeptide and polynucleotide sequences are carried out in different databases. Further, prior to the concomitant isolation and expression of a the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there many have been "classical" genetics papers which had no knowledge of the polypeptide but taught the gene. Search, therefore is not coextensive. As such, contrary to applicant's arguments, it would pose a substantial burden to search and examine the claimed polypeptides.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 84, 87 and 89 rejected under 35 U.S.C. 101 because they encompass non-statutory subject matter. The rejected claims recite mutant alleles or nucleic acids encoding mutant polypeptides and do not contain any language that indicates that the claimed molecules are isolated or in any way separated from the cells in which they would naturally be present. Thus, the currently rejected claims encompass structures that are found in nature. Because the claims read on polynucleotides that would occur in nature, untouched by the hand of man, these claims, as broadly drawn, encompass non-statutory subject matter. This rejection may be overcome by amendment of the claims to include, for example, language clarifying that the claimed nucleic acids are intended to be isolated and/or purified nucleic acids.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 84-90, 94-104, 109-112, and 126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 84 is indefinite because it is not clear what is meant when applicant claims "a variant allele." An allele is one of the different forms of a gene present in a particular nucleic acid sequence. It is not clear from the language of claim 84, however, if by claiming an allele

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applicant is claiming a full length coding sequence with particular changes or if applicant is claiming fragments which overlap with polymorphic positions, etc. The portion of the claim set forth after the transitional phrase “comprising” states that the claimed alleles has “a DNA sequence having variation in SEQ ID NO: 1,” however the claim does not set forth how much variation is permitted, the claim merely sets for the that the variation must comprise at least those listed in the claim. It is confusing, therefore, what is being claimed, and what is encompassed within the claimed invention. Furthermore, the nomenclature used to define the variation is also confusing and undefined. Neither the claims nor the specification define what is meant by the nomenclature, for example “T124A.” The claim appears to imply that the variation would be within SEQ ID NO: 1, at position 124, but turning to SEQ ID NO: 1, and counting to the 124th position, there is a guanine at this position, so it is confusing what is meant by this nomenclature. The claims would be immensely clarified if the location of the polymorphisms were given in some specific context. The following claim is an example of a claim which would overcome all of the preceding issues under 112 2nd paragraph:

An isolated nucleic acid wherein said nucleic acid comprises the DNA sequence of SEQ ID NO: 1, except that one or more of the following variations are present:

- (a) the “T” at position 279 of SEQ ID NO: 1 is replaced with a “C”;
- (b) the “T” at position 336 of SEQ ID NO: 1 is replaced with an “A”;
- (c) the “C” at position 365 of SEQ ID NO: 1 is replaced with an “T”;
- (d) the “G” at position 386 of SEQ ID NO: 1 is replaced with an “A”;
- (e) the nucleotides “GGC” are inserted following position 401 of SEQ ID NO: 1.

All claims which depend from claim 84 are indefinite for these same reasons.

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Claim 89 is similarly indefinite because the metes and bounds of this claim are unclear. Like claim 84, claim 89 is indefinite because it is not clear what is meant when applicant claims “a variant allele.” An allele is one of the different forms of a gene present in a particular nucleic acid sequence. It is not clear from the language of claim 89, however, if by claiming an allele applicant is claiming a full length coding sequence with particular changes or if applicant is claiming fragments which overlap with polymorphic positions, etc. The claim sets forth that the claimed allele encodes a receptor comprising “an amino acid sequence having a variation in SEQ ID NO: 2” however the claim does not set forth how much variation is permitted, nor how much of SEQ ID NO: 2 is required to be present in the claimed allele. This is compounded by the requirement that the encoded receptor merely is required to comprise “an” amino acid sequence having variation in SEQ ID NO: 2, which could be as few as two amino acids. The claim merely sets for the that the variation must comprise at least those listed in the claim. It is confusing, therefore, what is being claimed, and what is encompassed within the claimed invention. Furthermore, the nomenclature used to define the variation is also confusing and undefined. The claim requires that the variation “comprise” Ser23Pro, but does not define what this nomenclature means, nor does the specification define the nomenclature. The definition of the variation does not particularly refer to SEQ ID NO: 2, and since it is not clear from the preceding language of the claim how much of SEQ ID NO: 2 is required to be encoded by the claimed “variant allele” the metes and bounds of the claim, and the definition of the required variations is unclear. Claim 90 is indefinite for these reasons as it depends from claim 89.

Claim 104 is indefinite for similar reasons as claim 89.

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Claim 126 is also indefinite over the recitation in part (a) describing the allele of the receptor, for reasons as discussed for claim 84.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 84-90, 94-104, 109-112, and 126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to variant alleles of human mu opioid receptor genes as well as molecules that “selectively hybridize” to the same, as well as a kit comprising primers for the detection of the same. The claims as written are indefinite, as was discussed in the preceding rejections. In addition to being indefinite, the claims also lack written description because as they are written the claims require very little structural elements. Using claim 84 as an example, the preamble of the claim recites a “variant allele of a human mu opioid receptor” and the claim requires a DNA sequence “having variation in SEQ ID NO: 1”. The language of the claim is permissive of any possible amount of variation within SEQ ID NO: 1, provided that that variation comprise five specifically recited variants or combinations thereof. Thus, the claim does not require that the encoded receptor have any particular function, nor that it have any particular core sequence. Neither the claims nor the specification discuss what is necessary and

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essential for a sequence to be “a variant allele of a human mu opioid receptor gene,” that is, though the claims are permissive of any level of variation from SEQ ID NO: 1, there is no guidance as to how to identify which variants of SEQ ID NO: 1 are actually alleles of a human mu opioid receptor gene. There is no discussion as to how to identify which changes would or would not make the resultant variant still a “human” gene, nor which ones would or would now make the resultant variant a mu opioid receptor gene. Furthermore, many of the claims recite variant alleles that encode variant human mu opioid receptors that comprise “an amino acid sequence” having variation in SEQ ID NO: 2, and the use of “an” results in a claim sufficiently broad so as to require that the encompassed polypeptides encode only fragments of a sequence having a variation in SEQ ID NO: 2. The claims are extremely broad. Further, many of the claims do not even require the variant alleles, but only require sequences that are “selectively hybridizable” to the variant alleles, and these claims are even broader in nature since they encompass any molecule that would hybridize to the mutant alleles, including sequences from other mammals, or other organisms with mu opioid receptors, as well as fragments of SEQ ID NO: 1 itself.

Within this extremely broad genus of claims, applicant has provided only a limited number of examples. Applicants have taught that the known human mu opioid receptor is represented by SEQ ID NO: 1, and they have taught five novel variations of this sequence, namely (a) the “T” at position 279 of SEQ ID NO: 1 is replaced with a “C”; (b) the “T” at position 336 of SEQ ID NO: 1 is replaced with an “A”; (c) the “C” at position 365 of SEQ ID NO: 1 is replaced with an “T”; (d) the “G” at position 386 of SEQ ID NO: 1 is replaced with an “A”; and (e) the nucleotides “GGC” are inserted following position 401 of SEQ ID NO: 1. The

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claims however, encompass any number of additional variations within SEQ ID NO: 1, including any number of substitutions, deletions, inversions, insertions, and the like. The molecules provided in the specification are not representative of this broad genus because they represent only very small and specific changes to instant SEQ ID NO: 1, while the instant claims encompass, literally a change at any nucleotide within the sequence.

Thus, the claims are rejected for lacking proper written description.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 84-90, 94-104, and 109-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu (WO 95/07983; as cited in IDS).

Yu teaches a human mu opioid receptor gene comprising a DNA sequence having a variation in SEQ ID NO: 1, wherein said variation comprises an “A” at position 124 and a “T” at position 153. Yu teaches that their SEQ ID NO: 7 encodes a human mu opioid receptor (p. 111, lines 18-19). Turning to SEQ ID NO: 7 of the disclosure of Yu, this sequence is a encodes a human mu opioid receptor and has variation relative to SEQ ID NO: 1, for example, compare the first ten nucleotides of the two sequences. The sequence taught by Yu has an “A” at position 124 and a “T” at position 153, thus it appears to comprise variation as required by claim 84.

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With regard to claim 85, Yu specifically teaches “isolated and purified polynucleotides” including an isolated and purified polynucleotide comprising SEQ ID NO: 7 (p. 10, lines 12-15). With regard to claim 86, Yu teaches labels attached to the polynucleotides of the claimed invention (p. 36, line 35). With regard to claim 87, Yu teaches probes and primers that are fragments of their SEQ ID NO: 7, and these would all selectively hybridize to the variant that they teach (p. 32-37). With regard to claim 88, Yu teaches a label on the probes and primers (p. 36, line 35). Further, with regard to claim 87, Yu teaches the use of the rat mu opioid receptor cDNA to hybridize to and detect the human sequence. Thus, the rat sequence probe used by Yu was “selectively hybridizable” to the human sequence since it was used in a hybridization to select the human sequence (p. 107, lines 14-34). With regard to claim 89, the claim is broadly drawn to require only that the claimed allele encode a variant which comprises “an” amino acid sequence having a variation in SEQ ID NO: 2, and this could be any fragment of SEQ ID NO: 2 which comprises the variations listed in the claim. The variant allele taught by Yu encodes at least a Gly-Gly fragment (see 53-54 of encoded SEQ ID NO: 8). Thus, the gene taught by Yu encodes a receptor comprising “an” amino acid sequence having a variation in SEQ ID NO: 2 which is the addition of Gly following another Gly. Since the claim does not specifically and clearly set forth how much of SEQ ID NO: 2 is required and the claim does not specifically provide context for the recitation “Gly 63” the claim is interpreted as encompassing the molecule set forth by Yu. With regard to claim 90, Yu specifically teaches “isolated and purified polynucleotides” including an isolated and purified polynucleotide comprising SEQ ID NO: 7 (p. 10, lines 12-15). With regard to claims 94, 95, 96, and 97, Yu teaches a cloning or expression vector comprising SEQ ID NO: 7 and an origin of replication. Namely, Yu specifically teaches

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that the cDNA was cloned downstream of the human CMV promoter in a mammalian expression vector (p. 108, lines 15-18). Further with respect to claim 97, Yu teaches the rat mu opioid receptor gene with in a expression vector, and as previously discussed in this rejection, the rat gene is “selectively hybridizable” to the human variant (p. 99). With respect to claim 98 and 99, Yu teaches unicellular host cells transformed or transfected with an expression vector (see p. 108 and p. 99). With respect to claims 100, 102, 109, and 110, the nucleic acid taught by Yu has has an “A” at position 124 and a “T” at position 153, thus it appears to comprise two variations as required by the claim. Further, with regard to 102 and 110, Yu teaches the use of the rat mu opioid receptor cDNA to hybridize to and detect the human sequence. Thus, the rat sequence probe used by Yu was “selectively hybridizable” to the human sequence since it was used in a hybridization to select the human sequence (p. 107, lines 14-34). With regard to claims 101 and 103, as previously discussed, Yu teaches labeled molecules. With regard to claim 104, Yu teaches a molecule that encodes a receptor comprising “an amino acid sequence” having all of the variations required, where the claim is interpreted to require only a proline, a threonine, and a glycine following a glycine. The claim does not set forth any required context for the encoded sequence, it merely requires that it encode “an” amino acid sequence having the recited variations. With respect to claim 105, the nucleic acid taught by Yu has has an “A” at position 124 and a “T” at position 153, thus it has and would hybridize to molecules with this variation. Further, with regard to 102, Yu teaches the use of the rat mu opioid receptor cDNA to hybridize to and detect the human sequence. Thus, the rat sequence probe used by Yu was “selectively hybridizable” to the human sequence since it was used in a hybridization to select the human sequence (p. 107, lines 14-34). With regard to claim 109, 110, 111, and 112, Yu teaches the

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sequence within vectors and the vectors within host cells, as previously discussed in this office action.

Thus, the teachings of Yu anticipate the rejected claims.

9. Claims 84, 85, 87, 89, 100, 102, 104, and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US 5474796).

Brennan teaches an array that has thereupon every possible oligonucleotide of ten nucleotides, each as an isolated nucleic acid at a different position on the array (See Example 3, Col. 9). This rejection applies to the claims when they are interpreted so as to require only portions of the full length SEQ ID NO: 1, provided those portions have variations within them as recited in the claims. Since Brennan provides every possible combination of ten nucleic nucleotide probe on the array, Brennan teaches every possible variation within a fragment of instant SEQ ID NO: 1 or any other context. This rejection applies to the claims that require that the allele has "at least two variations" because the claim does not require any context for the variation. Thus, the claim is broadly interpreted as requiring only that particular nucleotides or encoded polypeptides are present in the sequence. Thus, Brennan anticipates the rejected claims.

10. Claims 87, 102, and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Bond et al. (PNAS USA, Vol. 95, p. 9608-9613, August 1998).

Each of the rejected claims require a nucleic acid molecule that is selectively hybridizable to a variant human mu opioid receptor gene, wherein the genes are variously described in the claims. The claims do not, however, require that the claimed molecules contain any particular sequence or overlap with a sequence, therefore, any sequence that would selectively hybridize to any portion of a variant humanmu opioid receptor gene is within the

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scope of these claims. Bond et al. teach primers for the amplification of the exons of the gene encoding human mu opioid receptors (p. 9609, 2nd column). These primers would selectively hybridize to isolated variant alleles of the human mu opioid receptor gene since they would hybridize to the gene for the amplification of the exons. This is considered "selectively hybridizing" because it is selective of the human mu opioid gene rather than other possible gene exons in a sample.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 126 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. (PNAS USA, Vol. 95, p. 9608-9613, August 1998) in view of Ahern (The Scientist, Vol. 9, No. 15, page 20, July 1995; computer print out provided, page numbers refer to the print out).

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Bond et al. teach primers for the amplification of the exons of the gene encoding human mu opioid receptors (p. 9609, 2nd column). These are PCR oligonucleotide primers suitable for detection of an allele comprising a human mu opioid receptor gene having any of the recited variations, since the one could amplify using these primers and then undertake further analysis to determine the actual nucleotides present. The claim does not require that the primers overlap with the variations, only that they are “suitable” for detection of an allele. These primers meet those limitations. Bond et al. also teach “other reagents” such as an agarose gel (p. 9609, 2nd column).

Bond et al. do not teach the packaging of these components into a kit which includes instructions.

Ahern provides a discussion of biochemical reagents kits, and teaches specifically that these “offer scientists good return on investment (title).” Ahern teaches there are many advantages to the purchase of biochemical kits, including that buying kits of premade reagents are convenient and save time, and that they include instructions (p. 4, second ¶). Thus, at the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to have packaged the reagents taught by Bond et al. into a kit including instructions for use so as to have provided a kit with the advantages expressly discussed by Ahern.

Conclusion

14. The prior art does not teach or suggest an isolated nucleic acid wherein said nucleic acid comprises the DNA sequence of SEQ ID NO: 1, except that one or more of the following variations are present:

(a) the “T” at position 279 of SEQ ID NO: 1 is replaced with a “C”;

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- (b) the "T" at position 336 of SEQ ID NO: 1 is replaced with an "A";
- (c) the "C" at position 365 of SEQ ID NO: 1 is replaced with an "T";
- (d) the "G" at position 386 of SEQ ID NO: 1 is replaced with an "A";
- (e) the nucleotides "GGC" are inserted following position 401 of SEQ ID NO: 1.

The position numbering in this claim has basis in the figures as originally filed which exemplify a context within SEQ ID NO: 1 where each of the recited variations occurs. The closest prior art, for example Bond et al. as cited herein provides variants of genes encoding human mu opioid receptors but does teach or suggest these particular variants. Though the specification does not discuss the effects of the mutations of (a), (b), or (e) on the function of the encoded polypeptide, an isolated nucleic acid wherein said nucleic acid comprises the DNA sequence of SEQ ID NO: 1, except that one or more of these variations is present would at least be useful for the detection of human mu opioid encoding genes. The variations recited in (c) and (d) do not change the sequence of the encoded polypeptide, and thus these molecules would also be useful for expressing the known, functional human mu opioid receptor.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

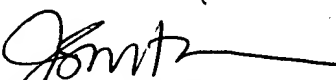
The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this

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application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Juliet C. Switzer
Primary Examiner
Art Unit 1634

June 23, 2005